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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,802	12/05/2003	Bryan Julien	020547-003560US	3275
20350 7590 06/27/2007 TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834			EXAMINER ROBINSON, HOPE A	
			ART UNIT 1652	PAPER NUMBER
			MAIL DATE 06/27/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/729,802	<b>Applicant(s)</b> JULIEN ET AL.	
	<b>Examiner</b> Hope A. Robinson	<b>Art Unit</b> 1652	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 April 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-12 and 21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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## **DETAILED ACTION**

### ***Application Status***

1. The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1652.
2. Applicant's response to the Office Action mailed February 12, 2007 on March 26, 2007 and April 12, 2007 is acknowledged. The Finality of the previous Office Action is withdrawn in favor of the Office Action below.

### ***Claim Disposition***

3. Claims 1-12 and 21 are pending and are under examination.

### ***Claim Objection***

4. Claims 6 and 9 objected to because of the following informalities:

Claim 6 is objected to for the recitation of "a polynucleotide of claim 1", instead of "the polynucleotide of claim 1". See also claim 9.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-12 and 21 are rejected under 35 U.S.C. 112, first paragraph, because the specification is not enabled for the full scope of the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. The enablement requirement refers to the requirement that the specification describe how to make and how to use the invention. There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue. These factors include, but are not limited to: Quantity of Experimentation Necessary; Amount of direction or guidance presented; Presence or absence of working examples; Nature of the Invention; State of the prior art and Relative skill of those in the art; Predictability or unpredictability of the art and Breadth of the claims (see *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988)). The factors most relevant to the instant invention are discussed below.

The claimed invention is directed to "an isolated recombinant polynucleotide that comprises a nucleotide sequence encoding at least one domain of a disorazole polyketide synthase (PKS), wherein said polynucleotide encodes a PKS domain having at least 98% sequence identity to the amino acid sequence of a domain of the disorazole polyketide synthase

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encoded by SEQ ID NO:1". Thus the claims encompass a genus of protein structures and the instant specification does not provide sufficient guidance/direction with respect to the genus. Moreover, no correlation is made between the structure and function of said proteins. Claim 1 for example, recites percent identity in association with a domain, only of a PKS encoded by SEQ ID NO:1. There are no indicia as to what domain is intended. Furthermore, neither the claims nor the instant specification sets forth what the function the encoded protein has. The claims encompass a large genus of proteins that are not adequately described which are intended to endow function to the encoded polynucleotide. Undue experimentation would be required for a skilled artisan to practice the claims the claimed invention commensurate in scope with the claims. Thus, applicants have not provided sufficient guidance to enable one of skill in the art to make and use the claimed invention in a manner that reasonably correlates with the scope of the claims, to be considered enabling.

6. Claims 1-12 and 21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claimed invention is directed to "an isolated recombinant polynucleotide that comprises a nucleotide sequence encoding at least one domain of a disorazole polyketide synthase (PKS), wherein said polynucleotide encodes a PKS domain having at least 98% sequence identity to the amino acid sequence of a domain of the disorazole polyketide synthase encoded by SEQ ID NO:1". The claims are directed to a genus of proteins that are not

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adequately described as a skilled artisan cannot envision the detailed chemical structure of the variants encompassed in the claims. The Court of Appeals for the Federal Circuit has recently held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as be structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials'. *University of California v. Eli Lilly and Co.*, 1997 U.S. App. LEXIS 18221, at \*23, quoting *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe a genus of genetic material, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these.

The specification fails to provide any additional representative species of the claimed genus to show that applicant was in possession of the claimed genus. A representative number of species means that the species, which are adequately described, are representative of the entire genus. The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, disclosure of drawings, or by disclosure of relevant identifying characteristics, for example, structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus.

In addition, no support was found in the instant specification for the recited language "wherein said polynucleotide encodes a PKS domain having 98% sequence identity to the amino acid sequence of a domain of the disorazole synthase encoded by SEQ ID NO:1". The specification discloses the following:

"In one aspect, the invention provides a polynucleotide comprising a sequence identical or substantially identical SEQ ID NO: 1 or its complement, or to a portion of SEQ ID NO: 1 or its complement encoding a domain, module, ORF, or region (e.g., as shown in Table 1). (Reference herein to SEQ ID NO:1 will be understood to refer also to the complementary nucleic acid sequence, except where clear from context that reference to a particular strand is intended.) In one aspect, the invention provides a polynucleotide comprising a sequence identical or substantially identical a fragment of SEQ ID NO:1 described in the Examples, *infra*, or a sequencing variant of SEQ ID NO: 1 described in the Examples, or a portion thereof encoding a domain, module, ORF, or region. As used in this context, two nucleic acid sequences (or two polypeptide sequences) are substantially identical if they have at least about 70% sequence identity, often at least about 80%, at least about 90%, at least about 95%, or even at least about 98% sequence identity". Applicant is required to cancel the new matter found in the claim.

Thus, one of skill in the art would be unable to predict the structure of other members of this genus based on the instant disclosure. Therefore, for all these reasons the specification lacks adequate written description, and one of skill in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

7. Claims 1-12 and 21 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter, which applicant (s) regard as their invention.

Claim 1 lacks clear antecedent basis for "said polynucleotide encodes a PKS". Note that the claim recites in the preamble, "an isolated recombinant polynucleotide that comprises a nucleotide sequence encoding at least one domain of a disorazole PKS". In addition, claim 1 is indefinite for the recitation of "PKS domain having at least 98% sequence identity to the amino acid sequence of a domain of the disorazole PKS encoded by SEQ ID NO:1" because percent identity should be followed by the sequence that it is identical to. The instant claim has percent identity to an amino acid sequence and the sequence provided is the DNA. Thus, the issue is that the percent identity is associated only with "a domain" of a PKS encoded by SEQ ID NO:1, said domain is not identified. See also claims 2-5 and 21 with the same language.

Claim 21 lacks clear antecedent basis for "said polypeptide".

***Response to Applicant's Arguments:***

8. Applicant's arguments have been fully considered. Note that new grounds of rejections have been instituted for the reasons stated above.

***Conclusion***



9. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, can be reached at (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hope Robinson, MS

Primary Examiner

HOPE ROBINSON  
PRIMARY EXAMINER